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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
FALK, ANNE MARIE				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/785,577

Applicant(s)

CHANG, LUNG-JI

Examiner

Anne-Marie Falk, Ph.D.

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1632

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

The request for continued examination filed September 5, 2008 has been entered. The amendment filed July 15, 2008 (hereinafter referred to as “the response”) has been entered. Claim 17 has been amended and Claims 29-50 have been cancelled. The remarks filed July 15, 2008 are considered herein.

Accordingly, Claims 17-20 remain pending in the instant application

The elected invention is drawn to a tumor cell composition comprising a tumor cell modified to express a B7-2 protein and at least one additional immune modulator, or a functional fragment of said B7-2 protein or said immune modulator. Applicants further elected GM-CSF as the cytokine species for prosecution.

Accordingly, Claims 17-20 are examined herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 15, 2008 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-20 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,548,068 (Schlom et al., priority to 6/7/95).

The claims are directed to a tumor cell composition consisting essentially of a tumor cell modified to express a B7-2 protein and at least one additional immune modulator. Dependent claims further specify that the immune modulator is a cytokine and that the cytokine is GM-CSF.

The transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis original). For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See MPEP 2111.03.

Schlom et al. disclose and claim a tumor cell modified to express B7-2 and GM-CSF. See especially Claims 1, 4, and 5. Claim 1 is directed to a host cell infected with a recombinant vaccinia virus which has incorporated into the viral genome a gene or portion thereof encoding B7-2. The claim further specifies that the B7-2 gene is expressed. Claim 4 is directed to the host cell according to Claim 1 wherein the recombinant virus further comprises one or more genes or portion thereof encoding an immunostimulatory molecule selected from the group consisting of IL-2, ICAM-1, LFA-3, CD72, GM-CSF, TNF α , INF γ , IL-12, IL-6 and combinations thereof. Claim 5 is directed to the host cell according to any one of Claims 1 to 4 “wherein the host cell is ...a tumor cell ...” Thus, the patent clearly discloses a tumor cell modified to express both B7-2 and GM-CSF, as instantly claimed. The reference further discloses that the recombinant vaccine composition may be used for gene therapy and that such an

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approach requires using cells from a given patient, inserting a gene encoding an immunostimulatory molecule such as B7-1, B7-2, IL-2, or GM-CSF into those cells, and administering the cultured cells back to the patient (column 1, lines 40-45). Thus, the patient receives genetically-modified autologous cells which minimizes or eliminates immunorejection of the introduced cells. This approach clearly discloses the production of an isolated primary tumor cell modified to express a B7-2 protein and at least one additional immune modulator, as instantly claimed.

Thus, the claimed invention is disclosed in the prior art.

At pages 3-4 of the response, Applicants assert that Schlom does not disclose a tumor cell composition consisting essentially of an isolated primary tumor cell modified to express B7-2 and at least one additional immune modulator. Applicants further assert that the compositions disclosed by Schlom all require expression of an exogenously transfected tumor associated antigen. Applicants go on to assert that the instantly claimed invention requires an isolated primary tumor cell which, because it is a primary isolate, does not express an exogenously transfected tumor associated antigen. Applicants are reminded that the term “tumor cell,” as recited in the instant claims, includes everything that may be expressed in or on a tumor cell and therefore does not exclude natural tumor cell components, such as a tumor-associated antigen. Likewise, the term isolated primary tumor cell does not exclude transfected components. The claim further recites that the isolated primary tumor cell is “modified” to express a B7-2 protein and at least one additional immune modulator. Clearly, the isolated primary tumor cell can be “modified” in any manner as long as it includes modifications to express B7-2 and at least one additional immune modulator. Moreover, where the claim recites the term “modified” it does not exclude additional modifications other than the B7-2 gene and another immune modulator gene. Accordingly, the instant claims read on the tumor cell compositions disclosed in the prior art. As noted above, the transitional phrase “consisting essentially of” will be construed as equivalent to “comprising” for purposes of searching for and applying prior art under 35 U.S.C. 102 and 103. See MPEP 2111.03.

At page 4 of the response, Applicants assert that Schlom requires an exogenously introduced tumor antigen, which is an element excluded by Applicant's use of isolated primary tumor cells. On the contrary, for the reasons discussed above, there is nothing in the present claims to exclude an exogenously introduced tumor antigen.

At page 4, paragraph 5 of the response, Applicants allege that Schlom does not disclose each and every element of the pending claims. On the contrary, Schlom et al. disclose an isolated tumor cell modified to express both B7-2 and GM-CSF, as instantly claimed. Nothing more is required.

Conclusion

No claims are allowable.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632